

The background features abstract, overlapping green geometric shapes in various shades of green, creating a modern and dynamic look. The shapes are primarily located on the left and right sides of the slide, framing the central text.

Ethylene Oxide (EO) Toxicity

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Themes for Today

- ▶ False Narrative about Dangers of EO
 - ▶ EO emissions are down.
 - ▶ No studies showing that EO in outdoor air can cause cancer.
 - ▶ Concern based entirely on “*hypothetical*” cancer risk estimates and failure to understand that they are NOT “actual” cancer cases.
- ▶ EO Protects Patients from Infectious Diseases
- ▶ Need to balance concern about “hypothetical” cancer risk estimates with “*real*” threat of delays in medical care or inadequate sterilization if more closures.

How Did We Get Here?

- ▶ Dec. 2016, EPA released a new EO cancer potency factor that was 30 times higher.
- ▶ Aug. 2018, EPA released National Air Toxics Assessment (NATA).
 - ▶ New cancer potency factor caused high EO cancer risk *estimates* in areas near EO sterilization plants and chemical plants in the NATA, even though emissions were down from previous NATA.
 - ▶ Elevated cancer risk "*estimates*" in NATA are misunderstood as being "*actual*" cancer increases.

NATA Causes Panic

► Headlines like these appear in the media:

“EPA finds high levels of cancer-causing chemicals near suburban...plant”

“Ethylene oxide levels high near...sterilization plants”

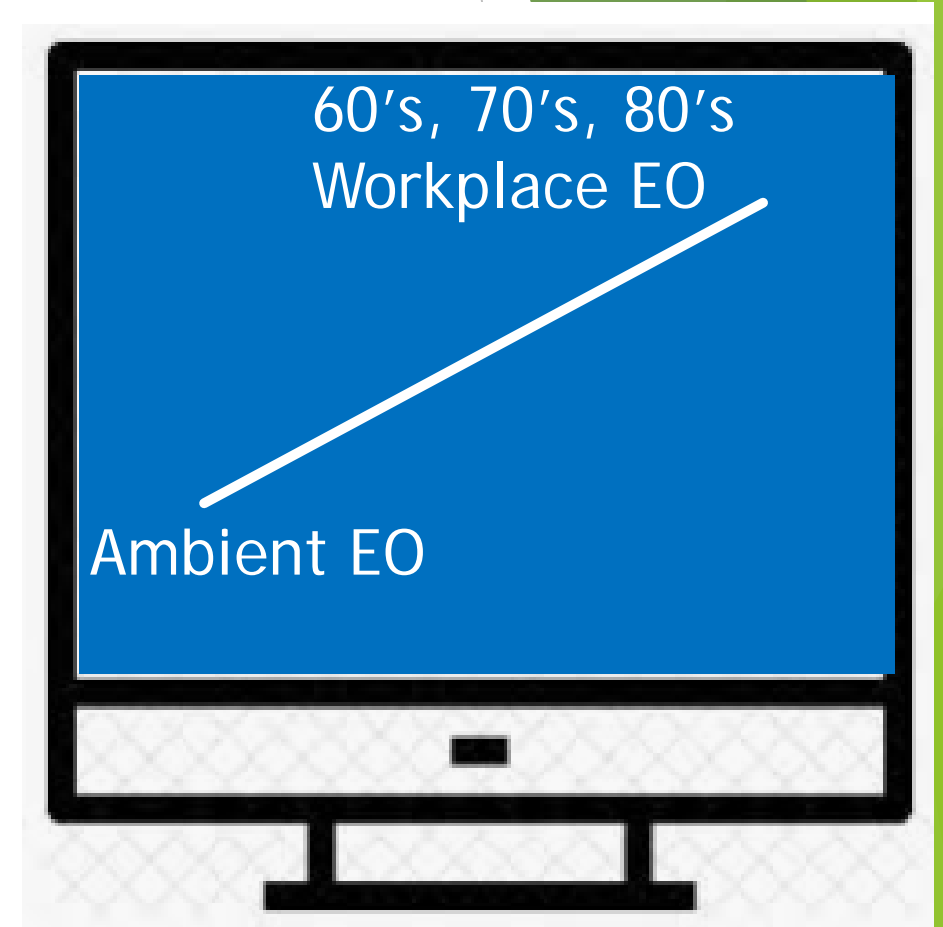
“Cancer-causing chemical in 2...communities leads to more cases of cancer experts say”

- IL plant closed in February, a plant in MI will end operations at end of year, 2 plants in GA have been temporarily closed.
- FDA warns of medical device shortages.



EO Cancer Potency Science is Uncertain and Evolving

- ▶ Potency Factor Not Based on New Scientific Data
- ▶ Potency Factor IS Based on New Cancer Estimation *Model*
 - ▶ Extrapolates cancer risk from high EO levels in workplace in 1960's to 1980's to much lower levels in today's outdoor air.
 - ▶ Shown to overpredict "actual" cancers in workers.
- ▶ No scientific studies showing levels of EO in the air across U.S. and near sterilization plants cause cancer.



New Cancer Potency Factor is Impractical

- ▶ Not Useful for Identifying Unsafe Levels of EO
 - ▶ Corresponds to EO concentrations that are lower than we can measure.
- ▶ Not Reasonable as a Health Standard
 - ▶ Naturally-occurring EO in the body is as much as 17,000 times EPA's potency factor.
 - ▶ Higher lymphoid cancer risk predicted than the observed lymphoid cancer from all causes.
 - ▶ EPA's cancer potency factor overpredicts *“actual”* cancer.

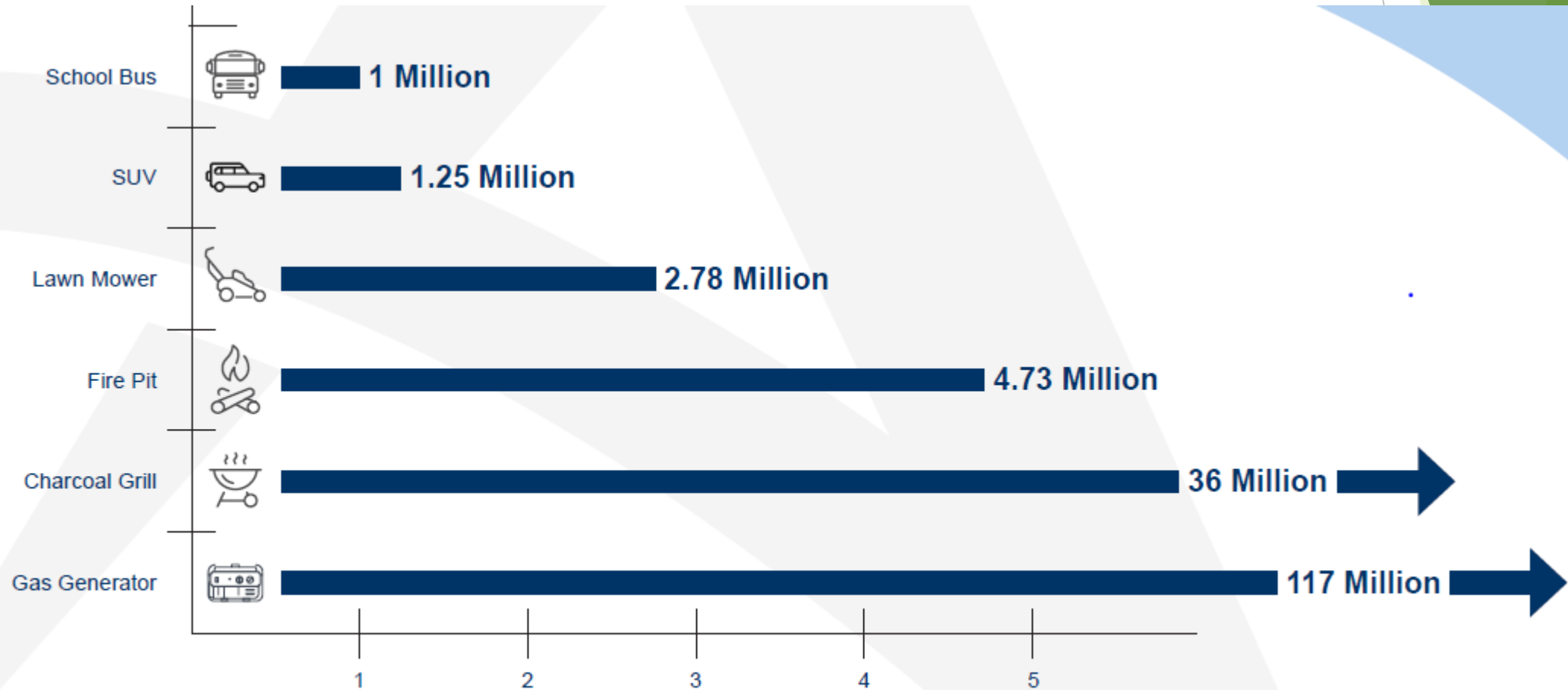
Exposure Dose and Duration Determine if Substance will be Toxic and What is Affected

Toxicant		Low or Short-Term Dose	High or Long-Term Dose
Ethanol (Booze)		Drunkenness/CNS Depression	Cirrhosis of Liver
Aspirin		Relieves Headache	Metabolic Acidosis Shock/Coma/Death
X-Ray Irradiation		Identifies Broken Bones	Leukemia and Other Cancers
Vitamin A		Supports Growth, Vision, Immune Function	Liver Damage, Pressure on Brain

Background Levels of EO (in absence of sterilization plants)



Everyday Items that Emit EO (short-term) above EPA's Cancer Potency Value



Times Higher than EPA's Ethylene Oxide Benchmark (1 part per 10 trillion)

Conclusions

- ▶ Heightened Concerns NOT Supported by Scientific Studies.
- ▶ EO levels near sterilization plants on average are similar to levels throughout the U.S.
- ▶ Further closures will cause medical device shortages.
- ▶ Concern about “hypothetical” cancer risk must be balanced with the “*real*” risk of inadequate sterilization and/or delays in medical care or inability to perform certain medical procedures if additional EO sterilization plants are closed.